

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
ETHICON WAVE 8 CASES LISTED IN PLAINTIFFS' EXHIBIT A	

**MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
GENERAL OPINION TESTIMONY OF CATHERINE MATTHEWS, M.D.**

Defendants Ethicon, Inc., Johnson & Johnson and, where applicable, Ethicon LLC (collectively, "Ethicon") submit this opposition to Plaintiffs' motion to exclude the general causation opinions of Catherine Matthews, M.D. (Dkt. 6887). Although Ethicon has designated Dr. Matthews as a general causation expert in the *Mullins* cases and each wave of this litigation since Wave 2, this is the first instance in which Plaintiffs have challenged her general causation opinions. Plaintiffs challenge the same types of opinions that Plaintiffs have challenged before with respect to other of Ethicon's pelvic surgeon general causation experts. Consistent with its adjudications of those other defense expert challenges, the Court should deny Plaintiffs' motion.

INTRODUCTION

A Professor of Obstetrics/Gynecology and Urology and Co-Director of an Integrated Pelvic Health Unit at Wake Forest University Medical Center, Dr. Matthews is Board certified in female pelvic medicine and reconstructive surgery, as well as obstetrics and gynecology. Ex. C to Pl's Mot., CV. She has extensive experience teaching residents and fellows on the risks and benefits of surgical treatment for stress urinary incontinence and pelvic organ prolapse, including training on the Instructions for Use ("IFU"). Ex. B to Pl's Mot., Expert Rpt. at 4. In 2015, Dr.

Matthews was selected to serve as one of eight national experts to administer the first oral board examination for Female Pelvic Medicine and Reconstructive Surgery. *Id.* at 2.

She has performed hundreds of surgeries using slings in her career to date (most of which have been Ethicon's TVT device); has delivered over fifty invited international lectures; and has published over sixty peer-reviewed articles on various subjects, including the utility of mesh slings at the time of robotic sacrocolpopexy and the outcomes of different techniques of prolapse repair. *Id.* at 2-6; Ex. C to Pl's Mot., CV. She was awarded the "Top 5% Reviewer" award by the American Journal of Ob/Gyn for her ability to understand and critique medical literature. Ex. B to Pl's Mot., Expert Rpt. at 3.

As set forth below, Plaintiffs' challenges to Dr. Matthews' opinions lack merit.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Matthews is entitled to testify about risks of implanting, whether those risks appeared in the IFU, and the common knowledge of physicians regarding risks.

The Court should allow Dr. Matthews to provide the same type of warnings opinions that it has allowed other experts to provide in this litigation. Dr. Matthews' qualifications are no different than all of the other pelvic surgeon experts in this case whom the Court has allowed to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *See, e.g., In re: Ethicon Inc.*, 2016 WL 4547053, at *3 (Dr. Grier).

Dr. Matthews' preeminent qualifications to testify about these issues is set forth in her CV and on pages 2-7 of her expert report. Ex. B & C to Pl's Mot. In fact, Dr. Matthews trains residents and fellows about IFUs. Ex. C to Pl's Mot., Expert Rpt. at 4.

The Court should also allow Dr. Matthews to testify about what risks are commonly known by surgeons, and therefore, need not be included in the IFU. The Court has expressed no opinion about expert testimony regarding “whether certain risks were common knowledge,” and therefore has not precluded this expert testimony. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) (“The plaintiffs’ Motion focuses on whether Dr. Woods is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge.”); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same, with respect to Dr. Drolet); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Serels); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Sepulveda-Toro); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493364, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Toglia); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Pramudji).

Other courts have recognized that expert testimony regarding the state of knowledge of the anticipated user is appropriate, indeed required, in warnings cases. *Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff’d*, 162 F. App’x 231 (4th Cir. 2006) (“[E]xpert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by

competent experts.”); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant).

Dr. Matthews is well qualified to testify regarding the risks that are within the common knowledge of surgeons who perform pelvic surgeries as set forth in detail in her CV and on pages 2-7 of her report. *See* Ex. B & C to Pl’s Mot. In addition, Dr. Matthews relies on her review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and general knowledge as a pelvic-floor surgeon in reaching her opinions. Ex. C to Pl’s Mot., Expert Rpt. at 32-37.

As a practicing surgeon who went through years of medical training, who has extensive clinical experience with pelvic floor surgeries, who teaches other physicians about these surgeries, and who keeps up with the medical literature, Dr. Matthews is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic floor surgeries. Indeed, only a physician with such training and experience *could* testify as to common knowledge of surgeons who perform pelvic surgeries.

Because Dr. Matthews has the qualifications and requisite foundation, she may offer her opinions about this topic.¹ Thus, Ethicon respectfully requests that this Court deny Plaintiffs’ motion to the extent it seeks to exclude Dr. Matthews’ testimony regarding the common knowledge of physicians regarding risks associated with pelvic floor surgery, and risks of implanting mesh and whether they were included in the IFUs.

¹ Moreover, this testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2, cmt. j, a product seller “is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users.” *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A, cmt. j. In fact, the FDA has said that information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device.” 21 C.F.R. § 801.109(c) (emphasis added).

II. The Court should reject Plaintiffs’ challenge to Dr. Matthews’ alleged “design and material properties” opinions.

Plaintiffs claim that Dr. Matthews is not qualified to testify that “polypropylene is inert, does not undergo mechanical changes or degraded, and that the material properties of polypropylene do not have any clinical significance” on the basis that she is not a design or material properties expert. Pl’s Mem., Doc. 6897 at 6. The Court should reject Plaintiffs’ argument for the same reasons that it has rejected Plaintiffs’ similar challenges to other defense pelvic surgeon experts.

In short, Dr. Matthews is not providing design and material properties opinions. On the other hand, she is qualified to opine about degradation and the clinical significance of polypropylene based on her significant clinical experience (in which she has not observed any clinically meaningful degradation), as well as her extensive review of scientific literature—including literature that Plaintiffs’ experts in these cases have cited. Ex. B to Pl’s Mot., Expert Prt. at 17-18, 20, 35-36. Dr. Matthews’ opinions are particularly bolstered by her review of Level 1 long-term studies, RCTs, systematic reviews, meta-analyses, and Cochrane reviews demonstrating the safety of polypropylene mesh, that the mesh is not degrading, and that, even if it did, there is no clinical significance. *Id.*

Dr. Matthews does not offer opinions about Ethicon’s process for developing products. Indeed, Dr. Matthews’ opinions about degradation are not at the molecular level and the equivalent of the opinions of polymer scientist, but instead, focused on clinical aspects of alleged degradation. *See Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *20 (S.D. W. Va. May 5, 2015) (“That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about ‘what’s happening at the molecular level’”).

In these MDLs, the Court has rejected these exact same challenges to other pelvic surgeon experts with similar credentials. *See, e.g., In re: Ethicon Inc.*, 2016 WL 4547053, at *3 (Dr. Toglia in Wave 1); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4556807, at *4 (S.D.W. Va. Aug. 31, 2016) (Dr. Flynn in Wave 1); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *45-46 (S.D. W. Va. Apr. 28, 2016) (Dr. Douso); *id.* at *5 (Dr. Galloway); *id.* at *33 (Dr. Culligan); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (Drs. Rosenzweig and Johnson); *Tyree*, 54 F. Supp. 3d at 550, 585 (Drs. Ostergard and Green).

Ethicon respectfully requests that this Court rule in the same manner in this wave of cases with respect to Dr. Matthews.

III. Dr. Matthews can reliably testify about the safety and efficacy of the devices based on her personal experience.

Finally, Plaintiffs claim that there is no reliable methodology for Dr. Matthews' assertions about certain of her clinical experiences as it relates to complications that her patients have sustained. Plaintiffs were welcome to explore these opinions with Dr. Matthews during her deposition but neglected to do so. There is no basis for Plaintiffs to challenge Dr. Matthews' recollection of her own experiences.

Further, this Court has found that a clinician expert who "does not offer expert testimony about precise rates, so he is not necessarily required to detail his experiences." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4547053, at *3 (S.D.W. Va. Aug. 31, 2016). Plaintiffs do not challenge any precise statistical opinions that Dr. Matthews has provided. There is no basis for Plaintiffs' challenge, and it should be rejected.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage

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